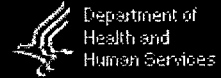


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**ATTACHMENT A****U.S. Food and Drug Administration**[FDA Home Page](#) | [CFSAN Home](#) | [Search/Subject Index](#) | [Q & A](#) | [Help](#)

July 10, 2003

**Consumer Health Information for Better Nutrition Initiative  
Task Force Final Report**[Return to Table of Contents](#)**Attachment A - Possible Regulatory Frameworks for Qualified Health Claims****Possible Regulatory Frameworks for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements****Public Health Impetus**

Dietary factors and sedentary lifestyles contribute substantially to the burden of preventable illnesses and premature deaths in the United States. Indeed, dietary factors are associated with 4 of the 10 leading causes of death: coronary heart disease, some types of cancer, stroke, and type 2 diabetes.<sup>(6)</sup> For example, high blood cholesterol is a major risk factor for coronary heart disease which can be modified by diet and other factors. Lifestyle changes that prevent or lower high blood cholesterol include eating a diet low in saturated fat and cholesterol, increasing physical activity, and reducing excess weight.<sup>(7)</sup> Fat intake in the United States as a proportion of total calories is lower than it was many years ago, but most people still eat too much saturated fat.<sup>(8)</sup>

In addition, there is growing concern about obesity and the appropriate health messages to address this unmet public health need. Persons who are overweight or obese are at increased risk for several chronic diseases.<sup>(9)</sup> In recent decades, there have been a number of public and private sector efforts in the United States aimed at reducing obesity. However, we have achieved only modest success with many of these efforts, and no success to date in reversing the alarming trend in the increase in numbers of people who are overweight or obesity in this country. For example, in 1999, an estimated 61% of U.S. adults were overweight or obese, with nearly twice as many overweight children and almost three times as many overweight adolescents as there were in 1980.<sup>9</sup> The tragic consequences of the current obesity epidemic has manifested itself in premature death and disability, in health care costs, in lost productivity, and in social stigmatization. Approximately 300,000 deaths a year in this country are associated with overweight and obesity, with an estimated total cost of \$117 billion in 2000.<sup>(9)</sup> Thus, finding more effective ways to improve consumer understanding and behavior is an

urgent public health priority.

The Food and Drug Administration (FDA) is aware that there are many opportunities to greatly improve public health beyond those that have been traditionally associated with the agency's product approval and enforcement activities. These opportunities have much to do with assisting the public in making wise dietary choices that benefit long-term health. When FDA's mission is properly understood to include this role, a number of possible strategies become evident, for example, challenging the industry to channel competitive energies into disseminating health information in food labeling and promoting food products on the basis of nutritional value, as well as simply taste, price, and amount.

In light of the need for improved consumer understanding and improved science-based competition among food and dietary supplement producers to promote better health, the Task Force recommends that the FDA announce a plan to establish, by regulation, procedures by which the agency will receive and evaluate petitions for use of qualified health claims in food and dietary supplement labeling. FDA should issue this document as part of its continuing effort to implement the Court of Appeals decision in *Pearson v. Shalala*, 164, F.3d 650 (D.C. Cir. 1999) (*Pearson*) and subsequent related decisions. This attachment presents several alternatives for regulating health claims that do not meet the "significant scientific agreement" (SSA) standard of evidence by which the health claim regulations require FDA to evaluate the scientific validity of claims. This attachment refers to two additional documents that are also attachments to the Task Force's Final Report: (1) Guidance: Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements, and (2) Guidance: Interim Evidence-based Ranking System for Scientific Data. The Task Force recommends that FDA proceed on an interim basis under these guidances until it can promulgate regulations through notice-and-comment rulemaking, as the Task Force also recommends. This attachment is intended to further the Consumer Health Information for Better Nutrition Initiative, announced by the agency on December 18, 2002, to encourage the flow of high quality, science-based information regarding the health benefits of conventional foods and dietary supplements.

## Legal Background

After the enactment of the Nutrition Labeling and Education Act of 1990 (the NLEA), FDA issued regulations establishing general requirements for health claims in food labeling (58 FR 2478, January 6, 1993 (conventional foods); 59 FR 395, January 4, 1994 (dietary supplements)). By regulation, FDA adopted the same procedure and standard for health claims in dietary supplement labeling that Congress had prescribed in the NLEA for health claims in the labeling of conventional foods (see 21 U.S.C. 343(r)(3), (r)(4)). The procedure requires the evidence supporting a health claim to be presented to FDA for review before the claim may appear in labeling (21 CFR 101.14(d), (e); 21 CFR 101.70)). The standard requires a finding of "significant scientific agreement" before FDA may authorize a health claim by regulation (21 CFR 101.14(c)). FDA's current regulations, which mirror the statutory language in 21 U.S.C. 343(r)(3)(B)(i), provide that this standard is met only if FDA determines that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by the totality of publicly available scientific evidence, including evidence from well-designed studies conducted in a manner consistent with generally recognized scientific procedures and principles (21 CFR 101.14(c)). Without a regulation authorizing use of a particular health claim, a food bearing the claim is subject to regulatory action as a misbranded food (see 21 U.S.C. 343(r)(1)(B)), a misbranded drug (see 21 U.S.C.

352(f)(1)), and for an unapproved new drug (see 21 U.S.C. 355(a)).

In *Pearson*, the plaintiffs challenged FDA's general health claims regulations for dietary supplements and FDA's decision not to authorize health claims for four specific substance/disease relationships. The District Court ruled for FDA (14 F. Supp. 2d 10 (D.D.C. 1998)). However, the U.S. Court of Appeals for the D.C. Circuit reversed the lower court's decision (164 F.3d 650 (D.C. Cir. 1999)).<sup>(10)</sup> The appeals court held that, based on the administrative record compiled in the challenged rulemakings, the First Amendment does not permit FDA to reject health claims that the agency determines to be potentially misleading unless the agency also reasonably determines that no disclaimer would eliminate the potential deception.

The Court of Appeals did not "rule out the possibility that where evidence in support of a claim is outweighed by evidence against the claim, the FDA could deem it incurable by a disclaimer and ban it outright." *Id.* at 659. Also, the Court saw "no problem with the FDA imposing an outright ban on a claim where evidence in support of the claim is qualitatively weaker than the evidence against the claim." *Id.* at 659 and n.10. This language was the genesis of the "weight of the evidence" criterion that FDA discussed in the October 2000 *Federal Register* notice and the December 2002 guidance.

In the *Federal Register* of October 6, 2000 (65 FR 59855), FDA published a notice announcing its intention to exercise enforcement discretion with regard to certain categories of dietary supplement health claims that do not meet the significant scientific agreement standard in 21 CFR 101.14(c). The notice set forth criteria for when the agency would consider exercising enforcement discretion for a qualified health claim in dietary supplement labeling, including as a criterion whether the scientific evidence in support of a given claim outweighed the scientific evidence against it.

In order for consumers to make healthy dietary choices across product categories, consistency in health messages is paramount. Thus, on December 18, 2002, FDA announced a new initiative to encourage the flow of high quality, science-based information regarding the health benefits of conventional foods and dietary supplements to consumers. In the *Federal Register* of December 20, 2002 (67 FR 78002), FDA announced that it would apply *Pearson* to health claims in the labeling of conventional foods as well as dietary supplements. The agency also announced the availability of guidance concerning when FDA intended to consider exercising enforcement discretion with respect to health claims that do not meet the standard of significant scientific agreement (SSA). Based on *Pearson*, the December 2002 guidance, like the October 2000 *Federal Register* notice included as a criterion whether the scientific evidence in support of the claim outweighs the scientific evidence against the claim.

Six days after publication of the December 20, 2002, notice and the guidance, the U.S. District Court for the District of Columbia issued its decision in *Whitaker v. Thompson*, 248 F. Supp.2d 1 (*Whitaker*). In *Whitaker*, the District Court, interpreting *Pearson*, found that "credible evidence," rather than "weight of the evidence," is the appropriate standard for FDA to apply in evaluating qualified health claims.<sup>(11)</sup> In light of *Whitaker*, FDA believes that the weight of the evidence standard in the October 2000 *Federal Register* notice and the December 2002 guidance must be tempered by the test of credible evidence. Communication of that, or any other level of evidence, to consumers in a non-misleading way remains of critical importance.

FDA also formed the Task Force on Consumer Health Information for Better Nutrition in part to develop a regulatory framework for FDA to reach informed, science-based decisions about health claims in a timely manner (see <http://www.cfsan.fda.gov/~dms/fl-ltr3.html>). In addition, the Task Force was charged with developing scientific guidance on how to apply an appropriate scientific standard and a consumer studies research agenda to assist the agency in presenting scientific information to consumers in a non-misleading way. On March 13, 2003, the Task Force established a public docket (Docket Number 03N-0069) to receive views and comments from interested stakeholders. This attachment is a result of the work of that Task Force and presents several alternatives for regulating qualified health claims. The Task Force recommends that, within a year, FDA initiate rulemaking proposing to establish regulations governing the procedures and scientific review criteria for such claims.

The Task Force believes that it would be premature to embark on such rulemaking now, for several reasons. First, the Task Force believes the agency should evaluate the various regulatory alternatives with the benefit of public comment and additional experience. Second, the Task Force believes it is also possible that stakeholders will recommend alternatives that FDA or the Task Force has not thought of but that may be better than the alternatives the Task Force has so far considered. In addition, the agency has developed a consumer studies research agenda. The results of this research should help FDA make consistent, empirically-based evaluations of whether the reasonable consumer will be misled by qualified claims in petitions and how best to convey the claim, and should enable FDA to provide clearer and more effective guidance to petitioners about how they can best develop such evidence related to their proposed claims. The studies may indicate that the evaluation criteria need to be revised or that the wording FDA is using to qualify claims needs improvement, and should enable FDA to consider rulemaking on an even more solid foundation.

Until any such rulemaking is completed, the Task Force recommends that FDA regulate qualified claims under guidance documents, based on enforcement discretion, providing (1) interim procedures for qualified health claims in the labeling of conventional human food and human dietary supplements, and (2) interim evidence-based ranking system for scientific data

### **Historical Basis for FDA Use of Interim Procedures**

The reason for the decision to apply *Pearson* to conventional foods is to provide consumers with better health/nutrition information so they can make better dietary choices. By making clear that manufacturers may label foods with truthful and non-misleading health claims, FDA believes that the guidance will precipitate greater communication in food labeling of the health benefits of consuming particular foods, thereby enhancing the public's health, because consumers will respond to health claims in food labeling. (67 FR 78003)

The decision announced in the December 2002 notice was also based on a desire to avoid further litigation over the constitutionality of the health claims provisions of the NLEA applicable to conventional food labeling to the extent that these provisions do not permit qualified claims. As explained above, the Court of Appeals held that, on the administrative record compiled in the challenged rulemakings, the First Amendment does not permit FDA to reject health claims that the agency determines to be potentially misleading unless the agency also reasonably determines that no disclaimer would eliminate the potential deception. In

*Pearson*, the agency, however, did not have any consumer data to show that a disclaimer would not eliminate the potential deception.

*Pearson* and subsequent related cases, including *Whitaker*, discussed above, concern dietary supplement labeling, but FDA's regulations for health claims for dietary supplement labeling are identical in all material respects to the NLEA provisions for health claims for conventional food labeling. Put another way, FDA adopted the same procedure and standard for health claims for dietary supplement labeling that Congress prescribed in the NLEA for health claims in conventional food labeling. These dietary supplement regulations, like the NLEA provisions in question, do not provide for qualified claims. Hence, based on *Pearson* and related cases, a court faced with a decision by FDA to not permit a qualified health claim for a conventional food might well find the same tension between the NLEA provisions and the First Amendment. It is possible that consumer data will show that potentially misleading health claims cannot be cured by disclaimers in at least some cases, but the agency does not have such data for conventional foods, as it did not (and does not) have such data for dietary supplements. Within the next year, the Task Force understands that the agency will be completing research in this area. The results of this research, together with further evaluation of the regulatory alternatives identified, and evaluation of any additional alternatives, should inform any rulemaking FDA initiates. In the interim, the Task Force recommends that FDA use the procedures and evidence-based ranking systems for scientific data set out in the guidance on these matters, and consider the exercise of enforcement discretion on a case-by-case basis with respect to qualified health claims in conventional human food and human dietary supplement labeling under certain circumstances. See *Heckler v. Chaney*, 470 U.S. 821 (1985); *Community Nutrition Institute v. Young*, 818 F.2d 943, 949-50 (D.C. Cir. 1987).

The Task Force believes that its recommended interim approach to qualified claims is a reasonable effort to combine the spirit of the NLEA with the current public health and legal circumstances, and one that reflects practical common sense. And, as the Court of Appeals for the District of Columbia Circuit observed in *Niagara Mohawk Power Corp. v. FPC*, 379 F.2d 153, 160, "Courts are loath to say that good sense is not good law."

### **The Federal Trade Commission (FTC) Requirement of "Competent and Reliable Scientific Evidence"**

The evidence-based ranking system presupposes that FTC's requirement of "competent and reliable scientific evidence" to substantiate an advertising claim related to health or safety has been met. FTC defines "competent and reliable scientific evidence" as "tests, analyses, research, studies, or other evidence" based upon the expertise of professionals in the relevant area, that has been "conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted" in the profession to "yield accurate and reliable results." *In Re: Great Earth International, Inc.*, 110 F.T.C. 188 (1988). The Task Force recommends that FDA consider scientific evidence only if it is competent and reliable.

### **Regulatory Framework for Unqualified Health Claims<sup>(12)</sup>**

All unqualified health claims remain subject to the statutory requirement of FDA authorization under the NLEA. Such claims are authorized by FDA pursuant to notice-and-comment rulemaking (21 CFR 101.70) and must meet the SSA standard (21 USC §343(r)(3)(B)(i), 21 CFR 101.14(c)).

## Current Regulatory Process for Qualified Health Claims

Since the October 2000 *Federal Register* notice and under the December 2002 guidance, when FDA decides to exercise its enforcement discretion with respect to a qualified health claim, it so notifies the petitioner by letter. There is no public participation.

This process was developed as a short-term response to the court decisions described above and has resulted in the agency making decisions on several qualified health claims involving dietary supplements. There is a need for transparent, long-term procedures with the force and effect of law. Such procedures would benefit both the industry and the consumer, provided they resulted in well-reasoned, predictable decisions that would facilitate non-misleading information reaching the consumer.

The Task Force has developed three regulatory alternatives (i.e. options) for FDA to consider:

- An option, which the Task Force recommends that FDA follow on an interim basis as a matter of enforcement discretion and which is consistent with the spirit of the NLEA by maintaining a premarket clearance system, provides for (a) FDA review of qualified claims and the supporting data, and (b) a measure of public participation. This option is similar in approach to the suggestions made by the Grocery Manufacturers Association and others in their comments on the December 2002 guidance on qualified health claims (comment # C-3, Docket Number 02D-0515). The process does not include informal (notice-and-comment) rulemaking, and the public would therefore not have an opportunity to comment on a proposal advanced by the agency. But, the requested qualified claim and the supporting data would be made available to the public for comment. The agency's decision on a qualified health claim would remain in the form of a letter and not, as some comments requested, in the form of a regulation. FDA could more readily revise or revoke the qualified claim if developing data indicated the need to do so. The data underlying qualified claims are, by definition, preliminary and subject to change as more studies are conducted. If the qualified health claim were established in a regulation, FDA could amend it only through time-consuming notice-and-comment rulemaking, and a claim that had become inaccurate or misleading because of new scientific developments would remain on labeling until the regulation was revised.
- Another option involves reinterpreting the SSA standard to apply to the claim (including the disclaimer, if any) instead of the underlying substance-disease relationship, so that the agency would focus on whether the words of the claim accurately reflect the data supporting it (e.g., "limited and preliminary scientific research suggest . . .") rather than whether there is SSA supporting the substance-disease relationship. Because the SSA requirement in FDA's health claim regulations (21 CFR 101.14(c)) tracks the language of the statute (21 U.S.C. § 343(r)(3)(B)(i)), and both require FDA to evaluate whether there is SSA that the claim is supported by the totality of publicly available evidence, it would not be necessary to amend 21 CFR 101.14(c) to implement this option; however, FDA would have to revoke its contrary interpretation of the statute and 21 CFR 101.14(c) in the preambles to the general health claim regulations. In those preambles FDA said that SSA was about the substance-disease relationship and not the words of the claim. Each qualified claim would then be required to undergo notice-and-comment rulemaking, which is the statutorily prescribed process for health claims for conventional foods. Requiring rulemaking before a qualified health claim is allowed on food labels is

consistent with suggestions made in a comment on the December 2002 guidance by Public Citizen and the Center for Science in the Public Interest (Docket Number 02D-0515). There is a concern that rulemaking for each qualified claim would not provide sufficient flexibility to implement changes in the claims necessitated by developing science and would be quite burdensome without any corresponding public health benefit. In addition, the reinterpretation of the SSA standard could be said to render it essentially meaningless because claims about any substance-disease relationship, no matter how weak or preliminary the evidence, would meet SSA as long as the claim accurately described the level of the evidence.

- A third option treats qualified claims as wholly outside NLEA and regulates the claims solely on a post-market basis, for being false or misleading. Consistent with FDA's past practice, "false or misleading" would be defined to include lacking substantiation. FDA could only evaluate and, where necessary, stop a claim after it was on a product label. This is similar to the FTC approach, but with one significant difference: FTC, unlike FDA, has administrative subpoena power, and so can obtain a company's substantiating data, evaluate the data and, where appropriate, take enforcement action relatively fast. Because FDA does not have administrative subpoena power, the agency would have to build enforcement cases by first searching the literature and consulting with experts. Depending on the nature of the matter, FDA would also have to test how consumers would interpret the claim (where, for example, there was a serious question about the existence of an implied claim). There is also a concern that this option would be inconsistent with the spirit of the NLEA, because it would not afford FDA any role in reviewing or clearing claims before they appeared in labeling and because it would not provide any opportunity for public participation. Finally, this option could be inefficient and too highly resource intensive for FDA to be able to protect consumers from misleading claims that would already be on the labeling of products in the marketplace.

### **Task Force Recommends that FDA Request Comment**

The Task Force recommends that FDA consider soliciting comments on each of the options set out above. The Task Force also recommends the agency obtain views relating to the strengths and weaknesses of each option from the perspective of public health, policy, law, and practicability; and which is the best option and why.

The Task Force suggests that FDA also request advice on how to provide incentives for manufacturers to encourage them to develop the data needed to obtain SSA for an unqualified health claim, and comments on how to develop more effectively public-sponsored research on substance/disease relationships.

Moreover, the agency has for decades discouraged or prohibited use of such phrases as "FDA approved" or "authorized by FDA," generally for one of two reasons: (1) all products of the type were FDA approved, so that a label statement regarding one product implied a difference that did not exist; (2) "approval" terminology was not appropriate because FDA did not approve any of the product type. The Task Force recommends that the agency request data or other information on whether a phrase indicating FDA authorization, e.g., "FDA says..." would encourage consumers to have more confidence in the claim that it accompanied than in a claim



without the phrase. Should such a phrase be encouraged at all, even if it gives the consumer confidence in the claim?

FDA could also remove the "may" from health claims that meet SSA, so that the uncertainty surrounding claims such as "calcium may reduce the risk of osteoporosis" is eliminated. The Task Force recommends that FDA ask whether the agency should make such a change. Should FDA make it a practice to authorize unqualified health claims by interim final rules thus making them available to petitioners on an expedited basis?

FDA has been requested on several occasions to consider accepting the evaluations of outside scientific groups as representing scientific consensus that could justify health claims. Some wanted to be able to convene their own groups of experts. Others wanted FDA to rely on such organizations as the American Heart Association or the American Dietetic Association, which evaluate scientific information and provide diet/health advice to their constituents. FDA has acknowledged the expertise of some of the non-governmental organizations, and the Task Force asks FDA to consider their recommendations as evidence of the strength of the science. However, to make such a system work fairly to the benefit of all, including consumers, FDA would need to have confidence in the scientific validity of the group's conclusions about the particular claim in question. Some groups would have more expertise than others, and FDA is not aware of a mechanism for evaluating them fairly and accurately. The Task Force suggests that FDA request comment on whether the evaluations of non-governmental groups should be given special weight in evaluating the strength of the science supporting a claim. If the agency should give weight to the evaluations of these groups, how should this weight be determined? On occasion, FDA has asked the experts in its Food Advisory Committee for scientific evaluations, but this system would not be able to actually conduct the scientific reviews needed for a particular substance/disease relationship. On an interim basis, FDA has chosen to use experts identified by another federal agency (i.e., Department of Health and Human Services (DHHS), Agency for Healthcare Quality and Research (AHRQ)) whose mission is to retain large numbers of such experts under contract. This process should provide the scientific expertise and additional resources that FDA needs to conduct its scientific reviews within acceptable time frames.

The Task Force suggests that FDA request comments on whether the agency should incorporate in its process for handling unqualified health claims under the SSA standard an option for issuing *interim* final rules within 190 days as a means of expediting the agency's processing of these petitions.

The Task Force also suggests that FDA request comments on how the agency could best educate consumers about the role of qualified health claims on food labeling, and how such claims may be used by consumers to advance their own understanding of diet and health matters.

### **Expanding Health Claims and Label Statements Beyond the Area of "Uncertain Science"**

There is interest in expanding the application of qualified health claims to areas beyond those related to uncertain science. Although the current and possible frameworks discussed here focus primarily on dealing with scientific data as a basis for qualified health claims, the Task Force recognizes that there may be merit in developing greater flexibility even in areas that do not relate to scientific uncertainty *per se*. Invoking more flexibility in administering the use of

health claims and dietary guidance statements would further advance the use of reliable diet and health information to consumers via labels on food.

The Task Force recommends that FDA solicit comment on the following, in particular:

- **Disqualifying Nutrient Levels.**

Under existing regulations (21 CFR 101.14(a)(4)), as a general rule a health claim is not allowed on a food label or in food labeling when the food possess a disqualifying high level of fat, saturated fat, cholesterol or sodium. However, when there is a public health benefit FDA has made exceptions to these disqualifying levels. For example, FDA authorized health claims for stanol and sterol esters in table spreads, products that contain more than 13 grams of fat per reference amount consumed. The Task Force recommends that FDA remain flexible and open to appropriate exceptions.

- **Minimal nutrient limits.**

Under FDA's general health claim regulations (21 CFR 101.14(e)(6)), a health claim may not be on a food label or in labeling for a food unless the food contains 10 percent or more of the reference daily intake or daily reference value for vitamin A, vitamin C, iron, calcium, protein, or fiber per reference amount customarily consumed prior to any nutrient addition. FDA has provided for some flexibility in that nutrients that have been added through fortification in accordance with FDA's fortification policy may be considered to meet the 10-percent requirement. Here again, additional flexibility may be in order for considering certain qualified health claims for foods that may not meet the strict limits of this regulation, when it is in the public interest to do so. FDA has received a petition from the National Food Processors Association on this subject. The agency plans to press forward in responding to this petition.

The Task Force recommends that FDA seek opportunities to exercise flexibility in its evaluation of health claim petitions in these and other areas where feasible, and that the agency also seek opportunities to promote the development and use of more dietary guidance statements on foods so that the US population can be encouraged to make better food choices and establish healthier eating patterns by making healthier food choices. The Task Force focused primarily on qualified health claims, but its discussions were enriched by considerations related to promoting partnerships with sister public health agencies and others so as to expand the universe of possible claims and labeling statements on conventional human foods and dietary supplements. Throughout the years, the federal government has worked to provide information to consumers about healthy eating patterns and wise food choices. Such advice originated with the Basic Four and has progressed through today's Dietary Guidelines for Americans and the Food Guide Pyramid. As these efforts move into more in-depth understanding and increasingly emerging science, as well as expand to encompass an array of stakeholders, they need to be encouraged and promoted by use of the food label.

To this end, the Task Force encourages FDA to work with sister agencies and stakeholders to identify the best, most appropriate, and most useful dietary guidance statements for consumers, and in turn provide for easy and meaningful ways that such information can appear in labeling.

(6) National Center for Health Statistics (NCHS). Report of final mortality statistics, 1995. Monthly Vital Statistics Report 45(11):Suppl. 2, June 12, 1997.

(7) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults. National Cholesterol Education Program: Second Report of the Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel II). Circulation 89:1329-1445, 1994.

(8) U.S. Department of Agriculture (USDA) and U.S. Department of Health and Human Services (HHS). Dietary Guidelines for Americans. 5<sup>th</sup> ed. USDA Home and Garden Bulletin No. 232, 2000.

(9) U.S. Department of Health and Human Services. 2002. The Surgeon General's call to action to prevent and decrease overweight and obesity. Rockville, MD: Public Health Service, Office of the Surgeon General. Available from : U.S. GPO, Washington.

(10) On March 1, 1999, the Government filed a petition for rehearing en banc (reconsideration by the full court of appeals). The U.S. Court of Appeals for the D.C. Circuit denied the petition for rehearing on April 2, 1999 (172 F.3d 72 (D.C. Cir. 1999)).

(11) In *Whitaker*, plaintiffs challenged FDA's refusal to permit a claim of a relationship between consumption of antioxidant vitamins (vitamins C and E) and reduced risk of contracting certain kinds of cancer. The agency found that the evidence weighed more heavily against than in support of the relationship, both qualitatively and quantitatively. As a result, FDA concluded that the claim was inherently misleading and, thus, could not be cured by a disclaimer. The district court disagreed. It found that the claim was only "potentially misleading," and that FDA had violated the D.C. Circuit's decision in *Pearson* by suppressing the claim rather than allowing it with a disclaimer.

In ruling that the claim was not "inherently misleading," the district court found that *Pearson* "implied, although it did not declare explicitly, that when 'credible evidence' supports a claim, that claim may not be absolutely prohibited." 248 F. Supp. 2d at 10 (citing *Pearson*, 164 F.3d at 659). The district court understood *Pearson* to state that only in a very narrow set of circumstances would a complete ban be permissible. *Id.* Thus, under the District Court's view of *Pearson*, FDA could have imposed an outright ban on a health claim only where there is either "no evidence" to support a claim or where the evidence for a claim is "qualitatively weaker than the evidence against the claim -- for example, where the claim rests on only one or two old studies." *Id.*, quoting *Pearson*, 164 F.3d at 659-660 and n.10 (emphasis in original). Even then, according to the District Court, a complete ban would be appropriate only when the government could demonstrate with "empirical evidence" that disclaimers "would bewilder consumers and fail to correct for deceptiveness \*\*\*." *Id.*, quoting *Pearson*, 164 F.3d at 659-60.

In the record before it, the District Court found, "some evidence" (248 F. supp. 2d at 13) -- approximately one-third of the more than 150 intervention and observational studies considered by the FDA -- supported plaintiffs' health claim. *Id.* at 11. An outright ban was therefore unreasonable because it was not supported by an overall review of the available evidence or by FDA's own guidance document. *Id.* at 13. In addition, the court stated, even if the scientific evidence against the antioxidant claim outweighed the evidence for the claim, FDA could not

ban the claim because the sixty-plus studies supporting the claim exceeded the *Pearson's* standard for determining when evidence supporting a claim may be deemed qualitatively weaker than the evidence against a claim -- when "only one or two old studies" support the claim (*Pearson*, 164 F.3d at 659 n.10). *Id.* Further, even if the evidence supporting the claim was qualitatively weaker than the evidence against it, FDA failed to provide "empirical evidence" that an appropriate disclaimer would confuse consumers and fail to correct for deceptiveness. *Id.*

(12) The term, "unqualified health claim" is used in this report to refer to health claims that meet the Significant Scientific Agreement (SSA) standard and are or could be authorized under the Nutrition Labeling and Education Act (NLEA) and regulations promulgated under that Act including 21 CFR 101.70.

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